UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.* ALLEN TIMOTHY YU Plaintiff, -against- GRIFOLS USA, LLC, GRIFOLS BIOLOGICALS LLC f/k/a GRIFOLS BIOLOGICALS, INC., GRIFOLS, S.A., GRIFOLS SHARED SERVICES NORTH AMERICA, INC. f/k/a GRIFOLS, INC. Defendants.	:	1:17-cv-2226-GHW MEMORANDUM OPINION & ORDER

GREGORY H. WOODS, United States District Judge:

Defendants Grifols USA, LLC, Grifols Biologicals, LLC, Grifols, S.A., and Grifols Shared Services North America, Inc. (collectively, "Defendants") develop pharmaceutical products which are used to treat patients who participate in United States government supported insurance programs, including Medicare. Relator, a former Quality Assurance Project Manager employed by Defendants, brings this action under the False Claims Act (the "FCA") on behalf of the United States, alleging that Defendants concealed and falsified information to obtain approval for its manufacturing plant in Los Angeles in order to receive reimbursement from and contracts with various government healthcare programs for Gamunex, an intravenous immunoglobulin drug produced at that plant. Defendants have moved to dismiss Relator's amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Because Relator has not alleged that statements made by Defendants to the government were material, as required by the FCA, Defendants' motion is granted.

I. BACKGROUND[1]

a. Factual Background

i. Statutory and Regulatory Background

In order to manufacture and sell a drug in the United States, a drug manufacturer must submit a new drug application ("NDA") to the Food and Drug Administration (the "FDA"). 21 U.S.C. § 355(a). An NDA proposes that the FDA approve a new drug for sale and marketing in the United States based on information submitted from the drug manufacturer, including clinical trial data and test results establishing the quality of the drugs manufactured at a specified facility. 21 U.S.C. § 355(b). One element of an NDA requires that manufacturers identify the production facilities and certify that they comply with the current Good Manufacturing Practice ("cGMP") regulations set forth in 21 CFR Parts 210, 211. FDA Form 356h, Application to Market a New Drug, Biologic, or An Antibiotic Drug For Human Use at 3.

Under the Food, Drug, and Cosmetic Act (the "FDCA"), the FDA "shall issue an order refusing to approve the application" if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. §§ 351(a), 355(d). In addition, the FDA may withdraw its approval of an NDA if the NDA "contains any untrue statement of material fact." 21 U.S.C. § 355(e).

The FDCA also prohibits the sale or manufacture of any drug that is "adulterated." 21 U.S.C. § 331(a). A drug is deemed to be "adulterated" if "the methods used in, or the facilities or

[1] The following facts are drawn from the Amended Complaint. Dkt. No. 52 (the "AC"). The Court "accept[s] all facts alleged in the [amended] complaint as true and draw[s] all reasonable inferences in the plaintiff's favor." *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 124 (2d Cir. 2008) (per curiam).

controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a). The FDA's regulations similarly provide that failure of a drug to comply with cGMP regulations, "shall render such drug to be adulterated" under the FDCA. 21 C.F.R. § 210.1.

ii. Grifols and IVIG Products

Plaintiff is the United States. AC ¶ 1. Relator, Allen Timothy Yu ("Relator"), is a resident of California and former employee of Defendants. *Id.* ¶ 2. Defendant Grifols, S.A. is a global supplier of plasma-derived products and pharmaceuticals headquartered in Barcelona, Spain, and is the parent company of the other Defendants. *Id.* ¶ 3. Defendant Grifols Shared Services North America ("Grifols Shared Services") is a Virginia corporation and a wholly owned subsidiary of Grifols, S.A., headquartered in Los Angeles, California. *Id.* ¶ 4. Grifols Shared Services is the parent of Defendants Grifols Biologicals, LLC and Grifols USA, LLC. *Id.* Relator worked for Grifols Biologicals, LLC ("Grifols Biologicals"), a Delaware company headquartered in Los Angeles, California, which manufactures intravenous immunoglobulin ("IVIG") in concert with and at the direction of Grifols USA, LLC. *Id.* ¶ 5. Defendant Grifols USA, LLC ("Grifols USA") is a Florida company headquartered in Los Angeles, California. *Id.* ¶ 6. Grifols USA collects human plasma from donors for use in manufacturing by Grifols Biologicals and also itself manufactures, markets, and sells other drugs, including Gamunex. *Id.*

According to Relator, "Grifols Shared Services, Grifols Biologicals and Grifols USA were subjected to pervasive control by Grifols, S.A." because, among other things, Grifols, S.A. "filed consolidated financial statements and consolidated statements of operations of its subsidiaries with the Securities and Exchange Commission" and because it "controlled the budgets of Grifols Shared Services, Grifols Biologicals and Grifols USA." *Id.* ¶ 13. Confidential witnesses ("CW"s) remarked

on the intertwined nature of the entities, noting, for instance, that they were "formally hired by Grifols Biologicals but . . . also performed work for other Grifols entities in the United States," *id.* ¶ 12, and that they "understood that [they] worked for either Grifols Biologicals and/or Grifols USA, but . . . received [their] compensation and a Form W-2 from Grifols, Inc.," *id.* ¶ 8. Relator further states that all defendants represent themselves "to the public as operating as one consolidated entity, and provide[] a uniform employee handbook for all Grifols' employees in the United States." *Id.* at ¶ 7.

iii. Grifols Seeks Approval of Plant to Produce Gamunex

In 2011, Grifols converted a manufacturing facility in Los Angeles (the "Los Angeles Plant") so that it could produce Gamunex, a pharmaceutical product in the IVIG category for treating chronic inflammatory demyelinating polyneuropathy and other autoimmune disorders. *Id.* ¶¶ 101, 104. The Los Angeles Plant conversion required the FDA to conduct a Pre-Approval Inspection audit of the facility and its equipment, and also to review Grifols' manufacturing validation records for IVIG products. *Id.* ¶¶ 105–06.

Defendants hired Relator in 2011 during the plant approval process to serve as a quality assurance project manager. *Id.* ¶ 2. His job was to perform routine and ad hoc quality assurance review of qualifications, investigations, documentation, audits, protocols and final reports on those topics that would be reviewed by the FDA. *Id.*

iv. Relator Discovers CIP IQ/OQ Discrepancies

In January of 2014, months before the planned FDA inspection of the Los Angeles facility, Relator discovered a discrepancy in the signed Installation Qualification ("IQ/OQ") Final Report for CIP-14, one of thirteen Clean-In-Place ("CIP") systems in the facility used to clean IVIG manufacturing equipment. *Id.* ¶¶ 107–08. During his examination of CIP-14, Relator noticed that a specific diaphragm control valve, which controlled how much of certain cleaning chemicals would be emitted, had been validated as stainless steel when in fact that valve was of "all plastic

construction." *Id.* ¶ 108. After raising that discrepancy with his supervisor, Colleen Moreno, Relator inspected the CIP-14 further and found that there were "at least 19 signed and dated entries in the CIP-14 IQ/OQ Report that did not agree with the actual equipment he found on the cleaning system." *Id.* ¶ 110. He told his Ms. Moreno about those discrepancies and she asked him to investigate the other twelve CIP systems. *Id.*

In the course of his inspections, Relator found over one hundred "discrepancies" in the CIP systems' hardware, components, and utilities. *Id.* ¶¶ 110, 112. These errors consisted primarily of incorrectly validated amperage for various parts; parts that had been previously validated with incorrect part numbers and model numbers that "were either not specified, not documented, or were documented but not actually found on the equipment" on previous reports; and missing, incorrectly documented, or undocumented identification tags on various parts. *Id.* ¶ 112. For instance, a phase reactor that supplied power to a pump motor drive "had 18 fundamental amps and not the 25 fundamental amps as required" by relevant protocol specifications. *Id.* In addition, three large valves were "incorrectly documented as having been tri-clamped, but Relator found that they were actually welded." *Id.* Certain "valve tags"—tags put on valves to identify the specific valve—had been validated as having been put on the valves when they had not been. *Id.*

According to Relator, those and other discrepancies "may lead to contamination of the IVIG equipment;" "may lead and [are likely] to lead to inaccurate testing results;" "may lead to contamination;" and "could impact [the CIP systems'] maintenance, service and, [sic] overall performance, thereby reducing the systems' efficacies, and leading over time to adulterated IVIG product and the significant risk of patient harm." *Id.*

Relator presented his findings to Ms. Moreno, who informed him that the matter needed to be elevated to her immediate supervisor, Eric Johnston, Grifols' Director of Quality Assurance. *Id.* ¶ 114. Mr. Johnston reported the findings to Sergio Molina, Grifols' Vice President of Quality Assurance, who contacted Catherine Kavanagh, Grifols' Director of Validation. *Id.* ¶¶ 115–16. Ms.

Kavanagh reported that the department might have been understaffed and the validation engineers probably did not do their work correctly. *Id.* ¶ 116. Mr. Molina stated that he did not want Relator's findings to be documented as a deviation or a corrective and preventative action, though Grifols' validation procedures required such documentation. *Id.* Relator was never interviewed by anyone at Grifols about his findings, nor was he aware of any investigation conducted by Defendants once he presented his findings. *Id.*

In March of 2014, Mr. Moreno asked Relator for his approval of various IQ/OQ reports that she said had been corrected. *Id.* Upon reviewing the updated reports, Relator saw notes that attributed the cGMP discrepancies to "inadvertent error." *Id.* He refused to approve them. *Id.* Later, during employment litigation Relator brought against Grifols, Relator saw that some reports appeared to contain his forged initials indicating his approval even though he had never signed those reports, as well as some errors that he had originally identified that had still not been corrected. *Id.* "To the best of Relator's knowledge," Defendants "made these falsified Final Reports available to the FDA for its pre-approval inspection of the Los Angeles Facility, and [Defendants] used these falsified Final [R]eports to create the summaries that Grifols submitted to the FDA." *Id.* ¶ 117.

v. Relator Comes to Believe that Defendants Falsified Rabbit Bacterial Endotoxin Tests

Relator "learned about significant fraud" regarding rabbit bacterial endotoxin tests in which rabbits injected with Gamunex had developed a fever. *Id.* ¶ 118. "[I]n connection with a conversation with Ms. Moreno," he came to believe that Defendants had concealed the results of these rabbit tests. *Id.* ¶ 118. Moreno told Relator that "behind closed doors with Kavanagh, [Ms. Kavanagh and Mr. Garcia] have been discussing the results for the rabbit tests on the IVIG Conformance Lots are so damaging [sic] that [Mr. Garcia] wants to delete them from [the Laboratory Information Management System]." *Id.* ¶ 118. According to Relator "Mr. Garcia and Mr. Kavanagh were apparently successful in fraudulently deleting data sets regarding the rabbit

testing and thereby concealed the same from the Government . . . as reflected by the fact that, upon information and belief, the LIMS currently does not contain any reference to these failed rabbit tests—even though, in 2014, it most certainly contained such data and test results." *Id.*

The FDA approved the Los Angeles Plant in January 2015. *Id.* p. 1. Relator does not allege that the approval has, at any point, been withdrawn.

vi. Confidential Witnesses' Experience at Grifols

Several CWs reported ongoing cGMP violations at the Los Angeles Plant. For instance, CW3, a Grifols human resources staff member from 2009 to 2016, conducted training at the Los Angeles Plant and learned that an employee had mistakenly dumped blood plasma down the drain instead of properly disposing of the hazardous material. *Id.* ¶ 127. When CW3 reported this to compliance personnel at Grifols, no corrective actions were taken. *Id.* CW5, a contractor and compliance auditor from 2018 to 2020, stated that engineers tested tanks all at once instead of separately, a shortcut in violation of cGMP's, which could have compromised the proteins in Gamunex. *Id.* ¶ 128. CW5 was also tasked with reviewing the functionality of Grifols systems and reported that the staff in the manufacturing department at the Los Angeles Plant were so busy that they did not have time to accurately complete and date required documentation as required by cGMP's. *Id.* ¶ 129.

CW6, a manufacturing technician from 2009 to 2017, regularly used incorrect components for the machines at the Los Angeles Plant per instruction from supervisors, a practice which violated cGMP's because it could lead to cross-contamination in Gamunex. *Id.* ¶ 130. CW6 communicated concerns about employees' lack of training and the risk of cross-contamination, but does not recall any corrective action being taken by Grifols. *Id.* ¶ 133.

vii. Gamunex is Recalled

CW5 also reported that the FDA audited the Los Angeles Plant in August and September 2019. *Id.* ¶ 135. CW6 learned about the recalls of Gamunex in 2019 from a friend who works at the

Los Angeles Plant and "assumed the conditions that led to the recalls were from cross-contamination . . . based upon the cGMP violations she/he regularly observed." *Id.* ¶ 134. During the audit, CW5 was excluded from a management meeting and it "became clear" to CW5 that key personnel were deliberately being "kept in the dark." *Id.* ¶ 135. Another employee told CW5 that the "exclusive nature of the meeting had to with 'certain outcomes,' which the managers wanted to discuss and achieve in private." *Id.* CW5 stated that "this 'felt sketchy.'" *Id.* CW5 also stated that the audit was "a basic, broad stroke [sic] because our manager had told us that we don't necessarily have enough time to look at every validation protocol and make sure everything's good." *Id.*

b. Procedural Background

On March 28, 2017, Relator filed a sealed complaint against Grifols USA, Grifols Biologicals., Grifols, S.A., and Grifols, Inc., Dkt. No. 1, which was unsealed on March 11, 2020. Dkt. No. 10. On March 11, 2020, the Government declined to intervene in this case after completing an investigation sparked by Relator's complaint in 2017. Dkt. No. 12. On July 22, 2020, Relator filed an amended complaint. Dkt. No. 52. The Amended Complaint names Grifols USA, Grifols Biologicals, Grifols, S.A., and Grifols Shared Services as defendants, collectively referring to them as "Grifols." *Id.*

In Count One of the Amended Complaint, Relator asserts violations of the FCA, alleging that Defendants knowingly and/or recklessly manufactured drugs in violation of applicable laws, making them ineligible for coverage under government healthcare programs. AC ¶¶ 140–49. In Count Two, Relator asserts claims for overpayments under the FCA and reverse false claims, alleging that Defendants submitted false and fraudulent claims, which allowed them to receive more reimbursement than they were entitled to ("overpayments"), that Defendants were required to reimburse the United States for the funds for which it was overpaid, and that Defendants knowingly made, used, or caused to be made or used, false records and statements to conceal the obligation to return the monies improperly obtained and retained. *Id.* ¶¶ 150–60. In Count Three, Relator asserts

a claim for fraudulent inducement under the FCA, alleging that Defendants induced the Government to approve their request to manufacture pharmaceuticals at their Los Angeles Plant and induced the Veterans Administration (the "VA") and TRICARE (the health care program for uniformed service members, retirees, and their families) to enter into contracts with it without disclosing the violations at its facilities, and that Grifols also induced the Centers for Medicare and Medicaid Services ("CMS") to enter into rebate contracts with it, leading to improper reimbursements by the United States government for the drugs. *Id.* ¶¶ 161–69.

Defendants together moved to dismiss the Amended Complaint under Rule 12(b)(6) on September 4, 2020. Dkt. No. 72; see also Dkt. No. 73 ("Mot. to Dismiss"). Relator opposed that motion to dismiss on October 5, 2020. Dkt. No. 74 ("Opp'n"). Defendants together replied on October 19, 2020. Dkt. No. 80 ("Reply").

II. LEGAL STANDARD

To survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Twombly*, 550 U.S. at 545).

A court must accept all facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Burch*, 551 F.3d at 124. But the Court is "not required to credit conclusory allegations or legal conclusions couched as factual allegations." *Rothstein v. UBS AG*, 708 F.3d 82, 94 (2d Cir. 2013). And a complaint that offers "labels and conclusions" or "naked

assertion[s]" without "further factual enhancement" will not survive a motion to dismiss. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555, 557). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *DeJesus v. HF Mgmt. Servs., LLC*, 726 F.3d 85, 87–88 (2d Cir. 2013) (quoting *Iqbal*, 556 U.S. at 678–79).

Claims brought under the FCA fall must be pleaded with "plausibility and particularity" under Federal Rule of Procedure 9(b). *Universal Health Svcs. Inc. v. United States ex rel Escobar*, 579 U.S. 176, 195 n.6 (2016) ("*Escobar*"). Under Rule 9(b), claims alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This "ordinarily requires a complaint alleging fraud to '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (quoting *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016)).

a. The Court Declines to Consider Exhibit A in Considering the Motion to Dismiss

As Exhibit A to its motion to dismiss, Grifols attached a purported "Prior Approval Statement" for the Los Angeles Plant that Defendants argue was submitted to the FDA and demonstrates that the Defendant "fully disclosed" the negative rabbit bacterial endotoxin tests. Dkt No. 69, 71. Plaintiff moved to strike Exhibit A from the record on September 26, 2020. Dkt. Nos. 75, 76 ("Mot. to Strike"). On September 27, 2021, the Court denied the Motion to Strike, noting that the Court would later determine whether to consider Exhibit A in deciding Defendants' Motion to Dismiss. *See* Dkt. No. 88 at 3.

The Court declines to consider Exhibit A in considering this motion. "In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d

Cir. 2010). "Where a document is not incorporated by reference, the court may never[the]less consider it where the complaint 'relies heavily upon its terms and effect,' thereby rendering the document 'integral' to the complaint." *Id.* (quoting *Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006)). "For a document to be considered integral to the complaint, the plaintiff must 'rel[y] on the terms and effect of a document in drafting the complaint . . . mere notice or possession is not enough.'" *United States ex rel. Foreman v. AECOM*, No. 20-2756-CV, — F.4th —, 2021 WL 5406437, at *10 (2d Cir. Nov. 19, 2021) ("*Foreman*") (quoting *Chambers v. Time Warner, Inc.,* 282 F.3d 147, 153 (2d Cir. 2002)). "And 'even if a document is "integral" to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document,' and it must be clear that 'there exist no material disputed issues of fact regarding the relevance of the document.'" *Id.* (quoting *DiFolco*, 622 F.3d at 111).

Here, Exhibit A is neither integral to the Amended Complaint, nor is its authenticity undisputed. First, Relator's allegations that the rabbit endotoxin tests were withheld from the FDA are based on his conversations with Associate Director Moreno. AC ¶ 118. There is no suggestion that Relator, in fact, relied on the contents of the PAS report to make that claim. *See Nicosia v. Amazon.com*, 834 F.3d 220, 234–35 (2d Cir. 2016) (holding that a document was not "integral" to a complaint where the plaintiff "neither mentioned nor relied upon" the contents of the document in drafting his complaint). And regardless, Relator disputes the accuracy and authenticity of Exhibit A. *See* Mot. to Strike 5–6. This dispute is sufficient grounds, regardless of whether Exhibit A is integral to the Complaint, to grant Relator's motion to strike Exhibit A. *Nicosia*, 834 F.3d at 235 ("[E]ven if a document is 'integral' to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document.") (quoting *Faulkner v. Beer*, 463 F.3d 130, 134 (2d Cir. 2006)). Accordingly, the Court declines to consider Exhibit A in determining this motion. *See Foreman*, 2021 WL 5406437, at *11–13. (holding that work orders and reports "not referenced" in

the complaint that were "possibl[y] disput[ed]" could not be considered in deciding a motion to dismiss).

III. DISCUSSION

A. The False Claims Act

The FCA was "originally adopted following a series of sensational congressional investigations into the sale of provisions and munitions to the War Department" during the Civil War "to stop the plundering of the public treasury." *United States v. McNinch*, 356 U.S. 595, 599 (1958). "Testimony before the Congress [at that time] painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." *Id.*

Accordingly, the FCA permits relators to bring suit, on behalf of the federal government, against parties who knowingly defraud the government. *See* 31 U.S.C. § 3730(b)(1) ("A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government."). The FCA "facilitates restitution to the federal government when money is fraudulently taken from it." *United States v. New York Soc. for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 CIV. 292 PKC, 2014 WL 3905742, at *8 (S.D.N.Y. Aug. 7, 2014).

The current version of the FCA creates civil liability where a defendant: (a) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); (b) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B); or (c) "conspires to commit a violation of" another subsection of the FCA, *id.* § 3729(a)(1)(C); *see also*, *Strock*, 982 F.3d at 58 (noting that the FCA imposes liability on one who "'knowingly presents, or causes to be presented, a

false or fraudulent claim for payment or approval,' or who 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'").

B. Relator Does Not Sufficiently Allege a Violation of Sections 3729(a)(1)(A) of (B) of the False Claims Act

1. Relator Does Not Allege that Any Claims for Reimbursement or Payment for Gamunex Contained Statements Material to Fraudulent Claims

Relator does not sufficiently plead that Defendants' claims for reimbursement for Gamunex produced in the Los Angeles Plant violated the FCA because his allegations fall short of stating that those claims contained records or statements material to a fraudulent claim. Before turning to a discussion of materiality, however, the Court briefly notes that Relator brings his claims under the "implied certification theory," which provides that

> when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim 'false or fraudulent' under § 3729(a)(1)(A).

Escobar, 579 U.S. 176, 180 (2016). Here, Relator alleges that Plaintiff failed to disclose violations of cGMP violations, rendering Defendant's claims for reimbursement fraudulent. Accordingly, analysis of materiality under the implied certification theory is appropriate.

In *Escobar*, the Supreme Court considered claims brought under the implied certification theory and emphasized that "the materiality standard is demanding," as "[t]he False Claims Act is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[2] *Id.* at 194 (quotations and citations removed). According to the Court, '[a] misrepresentation cannot be deemed material merely because the Government designates

[2] Prior to *Escobar*, circuit courts' positions regarding the implied certification theory were inconsistent: some altogether rejected liability under the theory, others permitted liability only where the defendant had failed to disclose violations that the government had expressly designated as a condition its payment of the claim, and others permitted liability even where the undisclosed violation was not expressly designated condition of payment. *Id.* at 186.

compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* "Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.*

Instead, the Court explained, "[w]hether a provision is labeled a condition of payment is *relevant to but not dispositive* of the materiality inquiry." *Id.* at 190 (emphasis added). It continued

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 194-95.

Thus, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Id.* at 193 (citing 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston)). "[U]nder *Escobar*, relevant factors in evaluating materiality include: (1) whether the government expressly designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; (2) the government's response to noncompliance with 18 the relevant contractual, statutory, or regulatory provision; and (3) whether the defendants' alleged noncompliance was 'minor or insubstantial.'" *Foreman*, 2021 WL 5406437, at *13. "Materiality must also 'be pleaded with particularity under Rule 9(b).'" *Id.* (quoting *Grabcheski v. Am. Int'l Grp., Inc.*, 687 F. App'x 84, 87 (2d Cir. 2017)).

i. Payment is Conditioned on FDA Approval, and Not cGMP Compliance

The first *Escobar* factor—whether the Government has expressly identified a provision as a condition of payment—weighs against a finding of materiality because payment is conditioned on FDA approval, which has been granted and never withdrawn, rather than cGMP compliance. Plaintiff repeatedly concedes that FDA approval—not cGMP noncompliance—conditions the

government's payment. *See, e.g.*, AC ¶ 87 (alleging that reimbursement by the Veterans Administration relies on the "quality assurance" of drug products by the FDA) (citing 48 C.F.R. § 46.408); *id.* ¶ 65 ("Medicaid expressly limits coverage of outpatient drugs to those that meet all the requirements and conditions of FDA-approval . . . ."); *id.* ¶ 62 ("Medicare does not pay . . . if FDA [sic] determines that a required NDA has not been approved or that the drug is misbranded or adulterated."); *id.* ¶ 79 ("To be a 'covered drug' eligible for payment under TRICARE, the product must . . . be 'approved for safety and effectiveness' . . . under the FDCA.") (citing 32 C.F.R. 199.21(q)(2)(iii); 38 U.S.C. § 8126(h)(2)); *id.* ¶ 98 ("Eligibility for Government payment for drug products purchased by the VA is . . . fully integrated with the Government's requirements . . . under the FDCA, including securing FDA approval to market the drug product."). By alleging as such, Relator does not meaningfully contest that FDA approval has been expressly identified as the condition of government reimbursement.[3] Indeed, Relator does not identify in the Amended Complaint or in the Opposition any provision that expressly identifies cGMP compliance as a condition of payment. Without a more express designation of cGMP compliance as a condition of payment by the various government programs, this factor weighs against a finding of materiality. *See Foreman*, 2021 WL 5406437, at *14 (finding this factor weighed "at most . . . neutrally in the materiality analysis" where there were "no provisions in [a] contract or in the federal regulations specifically designating any of the contractual or regulatory requirements that Foreman alleges [the defendant] violated as an express condition of payment").

Relator's argument that *Escobar* "rejected" Defendants' "payment condition argument" Opp'n 10, misapprehends *Escobar*'s holding. *Escobar* clarified that courts should consider, as one of numerous factors, whether a defendant failed to disclose a violation that the government had

[3] To the extent Relator claims that the government programs would refuse to reimburse for the drugs because the Los Angeles Plant should not have received FDA approval in the first place, those arguments are addressed below. *See infra* Part III(B)(2).

expressly designated as a condition of payment—it did not reject consideration of it altogether. *See Strock*, 982 F.3d at 62 (considering express designation as the first factor in its materiality analysis). Thus, while this factor is not dispositive, it is still relevant to the Court's materiality analysis.

As follows, the Court gives some weight to Relator's argument that cGMP compliance is "embedded in the FDCA and FDA regulations," such that Defendants' alleged cGMP violations are "'evidence' of materiality," *see* Opp'n 10-11—but that argument is not sufficient to meaningfully tip this factor in favor of materiality. Relator points to regulatory guidance and program manuals that emphasize that drugs reimbursed for or purchased by the program should be safe and not adulterated. *See, e. g.*, AC ¶ 62 (citing a Medicare Benefit Policy Manual stating that "the Secretary must consider the ability of the applicant to ensure product integrity. We propose that the evaluation include, but not be limited to, the applicants' ability to assure that products are not adulterated, misbranded, spoiled, contaminated, expired, or counterfeit."); *id.* ¶ 92 (noting that, under Veterans Administration and Department of Defense guidance, cGMPs are the "quality standard applied to [the] industry for the manufacturing, processing, packaging or holding of medical products. . . ."). These and other similar allegations confirm that the various programs aim to ensure the quality of a drugs for which they reimburse, and suggest that cGMP compliance contributes to that overall quality. However, as *Foreman* counsels, such "[g]eneric and routine appeals to the importance of . . . broad goals" do not significantly impact the court's analysis of this factor because they "do not put a contractor on notice of the importance of a given requirement to the government's payment decision, particularly where . . . the government has not expressly designated compliance with that requirement as a condition of payment." *Foreman*, 2021 WL 5406437, at *14. Thus, while the Court recognizes that cGMP compliance plays a role in the regulatory landscape governing the government's decision to reimburse for Gamunex, ultimately, payment is not expressly conditioned on cGMP compliance. Thus, Plaintiff has not sufficiently alleged that the first factor weighs in favor of materiality.

ii. The Government's Response to Similar Misrepresentations Weighs Against Materiality, since the FDA has not Withdrawn its Approval of Gamunex

The government's response to similar misrepresentations also weighs against materiality. Most notably, despite the government's knowledge of this litigation—which has been pending for over four years—the FDA has never withdrawn its approval of Gamunex produced in the Los Angeles Plant. As such, it has continued to make payments and reimbursements for the drug. Where "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Escobar*, 579 U.S. at 195. "Such very strong evidence becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.,* 865 F.3d 29, 35 (1st Cir. 2017) (citing *Escobar*, 579 U.S. at 195). Here, that the FDA has had a significant period of time to investigate and withdraw its approval, but has not done so, weighs against a finding of materiality.

Relator asks the Court look to the Ninth Circuit's decision in *United States ex rel. Campie v. Gilead Sciences*, *Inc.*, 862 F.3d 890 (9th Cir. 2017), where the Ninth Circuit determined that a relator sufficiently alleged materiality despite continued FDA approval of the drug at issue; that case, however, can be distinguished from the facts in this case. In *Campie*, the relator alleged that the defendant had concealed its use of an "unapproved and contaminated" product from a non-compliant foreign facility when manufacturing the drug product at issue. *Id.* at 902–03. The relator in *Campie* alleged significantly more indicia that the government viewed the use of that contaminated product as material. For instance, there, the FDA had undertaken an inspection of the facility after it learned of the noncompliance, and also issued a "noncompliance letter" that specifically identified and addressed the alleged violations. *Id.* at 906. Here, there are no particularized, non-speculative

allegations that the Government expressed concern regarding the alleged cGMP violations.[4] Moreover, in *Campie*, the drug manufacturer stopped using the allegedly non-compliant materials to manufacture the drugs in question, *id.*, whereas here, there are no allegations that the violations here have ceased. As *Campie* acknowledged, "[o]nce the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance." *Id; see also United States ex rel. Kelly v. Serco, Inc.,* 846 F.3d 325, 334 (9th Cir. 2017) (dismissing false implied certification claims where the military continued to pay claims related to a wireless communications project even though it knew about alleged ongoing reporting violations).

Relators "face an uphill battle in alleging materiality" where "at all relevant times, the drugs at issue [are] FDA-approved." *Campie*, 862 F.3d at 905. Here, Relator has not sufficiently alleged facts to show that the second factor weighs in favor of materiality given the FDA's continued approval of Gamunex, despite the government's awareness of Relator's allegations.

iii. Due to the Speculative Consequences of Alleged Noncompliance, Relator's Alleged Noncompliance is Minor and Insubstantial

The final factor—whether the alleged noncompliance was minor or insubstantial—similarly weighs against a finding of materiality. This factor concerns "whether the Government would have attached importance to the violation in determining whether to pay the claim." *Marsteller ex rel. United States v. Tilton*, 880 F.3d 1302, 1313 (11th Cir. 2018). "'[B]road appeals' to the importance of a given regulatory requirement 'cannot clear the rigorous materiality hurdle.'" *Foreman*, 2021 WL 5406437, at *18 (quoting *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 542 (10th Cir. 2020)).

[4] Relator points to the fact that the FDA recalled Gamunex twice in 2019 and avers that a confidential witness "assumed" the conditions leading to the recalls were caused cGMP violations. AC ¶ 134. Relator also notes that the FDA audited the Facility in 2019, alleging only that the audit "focused on" those recalls. *Id.* ¶ 135. These allegations are far more speculative than the FDA actions that specifically targeted the noncompliance in *Campie*, and lack sufficient particularity under the Rule 9(b) pleading standard for materiality. Thus, the Court attributes little weight to the allegations.

Relator does not allege that any of the alleged cGMP violations have, in fact, led to any adverse impact on Gamunex's quality. Instead, Relator alleges only that such violations "may" or "could" have negative consequences. For instance, he alleges that the incorrectly specified amperage "may lead" to contamination of equipment, that the failure to verify certain valves "could result in" certain systems "not functioning as designed," and that certain violations would lead "over time to adulterated IVIG product." AC ¶ 112. He similarly avers that the failure of the rabbit endotoxin test—which Defendants allegedly concealed from the FDA—"caused Relator to become concerned" because the tests "likely" reflected contamination. *Id.* ¶¶ 118–19. Viewing these speculative allegations in light of the fact that the FDA has not withdrawn its approval for Gamunex, Relator's claims fall short of suggesting that the alleged noncompliance with cGMPs is so substantial as to impact the government's decision to reimburse and pay for Gamunex produced in the Los Angeles Plant. *See Foreman*, 2021 WL 5406437, at *19 (finding noncompliance was insubstantial where, based on the allegations in the complaint, it was "not apparent that [the noncompliance] affected [the defendant's] ability to provide . . . services" required under the contract at issue); *cf. Janssen*, 949 F.3d at 543 (finding that noncompliance was insubstantial where there was "'little evidence' demonstrating the extent" to which the alleged noncompliance impacted the government's payment decisions). Thus, Plaintiff has not alleged sufficient facts to suggest that this factor weighs in favor of a finding of materiality.

Accordingly, the *Escobar* factors weigh against a finding of materiality, and Plaintiff has not sufficiently alleged that the alleged cGMP violations are material to the Government's decision to reimburse and pay for Gamunex. Because Plaintiff must plead materiality to succeed on his claim, but has not done so, the Court need not consider the other elements required to state an FCA claims—namely, falsity and causation.

2. Relator Does Not State a Fraudulent Inducement Claim on the Basis that the FDA's Approval was Fraudulently Obtained

i. The Fraudulent Inducement Theory is Inapplicable to Relator's Claims Regarding FDA Approval

Relator brings a claim that FDA approval was wrongfully obtained under the fraudulent inducement theory, AC ¶¶ 161–69, but there is no support for Relator's theory the fraudulent inducement theory is applicable to cases where the parties did not enter into a contract. Under fraudulent inducement theory, "FCA liability attaches not because a defendant has submitted any claim for payment that is 'literally false,' but instead because 'the *contract* under which payment [is] made is procured by fraud.'" *Strock*, 982 F.3d at 60 (quoting *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467–68 (5th Cir. 2009)) (emphasis added) (alteration in original); *see also*, *Foreman*, 2021 WL 5406437, at *20 n.9 (discussing fraudulent inducement claims brought on the basis of the parties having entered into a contract). Claims brought under the fraudulent inducement theory are analyzed under the same materiality analysis under *Escobar* as are those brought under the implied certification theory. *See Strock*, 982 F.3d at 60–66 (analyzing fraudulent inducement claims under the *Escobar* factors).

Relator has not cited to a single case where fraudulent inducement has been sufficiently alleged that did not involve parties that had entered into a contract.[5] Moreover, at least one court has expressly rejected arguments that fraudulent inducement theory applies in cases where there is no contractual agreement at issue. *See In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig. (No. II),* 332 F. Supp. 3d 927, 952 (D. N.J. 2017) ("Fraud-in-the-inducement began in the Supreme Court's *Hess* decision as a doctrine applicable to contracts induced by fraud. It was reaffirmed by Congress in the legislative history of the 1986 Amendments to the FCA as a doctrine limited to claims under a

[5] The only case Relator cites in support of his fraudulent inducement theory for FDA approval, *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 83 (2d Cir. 2017), was not pleaded under the fraudulent inducement theory, but instead involved a scheme to submit false records to the government.

contract, loan guarantee, or other agreement. And it has only ever been applied by the Courts of the Third Circuit . . . to contracts induced by fraud.") (citations and quotations marks omitted). At minimum, then, there is a significant dearth of support for Relator's fraud in the inducement theory regarding FDA approval.

Aside from lacking precedential support, Relator's allegations under the fraudulent inducement theory are difficult to square with the plain language of the FCA. The FCA imposes civil liability on persons who "present[] . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a). A claim is defined as "any request or demand, whether under a contract or otherwise, for money or property." 31 U.S.C. §3729(b)(2). This language most plainly requires that the defendant request some form of tangible payment from the government. *Cf. Strock*, 982 F.3d at 61 ("FCA materiality analysis can encompass a misrepresentation's impact on the government's decision to *do business* with a defendant in the first instance.") (emphasis added). FDA approval does not entitle an entity to such a tangible payment, and at least one other Circuit has denied such claims on that basis. *See D'Agostino v. ev3, Inc.,* 845 F.3d 1, 7 (1st Cir. 2016) (rejecting a FCA claim based on allegedly fraudulently-obtained FDA approval in part because "[t]he FDA . . . made none of the payments at issue in this lawsuit. Rather, CMS made the payments . . . ."). In short, Relator's fraudulent inducement theory based on FDA approval lies on a shaky legal foundation. [6]

Even if Relator's theory is cognizable, Relator does not sufficiently allege the concealed cGMP violations were material to FDA approval largely for the same reasons that he does not state a claim under the implied certification theory for government reimbursement. *See Foreman*, 2021 WL 5406437, at *20 n.9 (commenting that, where a relator's "fraudulent inducement claim and his other

[6] Though Relator expressly alleges FDA approval as grounds for his fraudulent inducement claim in the Amended Complaint, *see* AC ¶¶ 162–63, he does not argue that his theory of fraudulent inducement is based on the FDA's approval in his Opposition. *See* Opp'n 24. Instead, he argues only that the "AC identifies specific contractual relationships with the Government that the Government would not have entered into had it been aware of the serious cGMP violations concealed by Defendant." *Id.* The lack of mention in the Opposition of FDA approval as grounds for his fraudulent inducement claim implies that Relator may recognize the faults in his theory.

[FCA] claims rest on the same alleged violations," the relator's "fraudulent inducement claim . . . rises and falls with his other [FCA] claims"). The first materiality factor—the failure to disclose a violation that was expressly designated as condition of payment—cannot be readily applied to Relator's theory since, as previously discussed, the FDA did not pay for Gamunex. As to the third factor, Relator falls short of alleging that the violations were not minor or insignificant, as previously discussed. *See supra* Part II(B)(3).

The second factor—the government's response to the alleged violation—bears particular significance here, given the FDA has not withdrawn its allegedly fraudulently obtained approval. *See D'Agostino*, 845 F.3d at 8 ("The FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained."). Permitting Relator to maintain an action on the bases pleaded here could "turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Id.* at 8; *In re Plavix*, 332 F. Supp. 3d at 959 ("[T]he regulatory agency's real-world conduct after having obtained actual knowledge of the fraud must be alleged as evidence in any FCA fraud-on-the-agency style claim. . . ."). Given that Relator alleges only speculative harms resulting from the alleged cGMP violations, the Court sees no basis in Relator's allegations to supplant the FDA's decision-making with that of a court or jury. Accordingly, Plaintiff has not adequately alleged a claim under fraudulent inducement theory as pertains to FDA approval.

3. Relator Does Not State a Fraudulent Inducement Claim as Relates to Defendants' Obtaining Contracts with Various Government Programs

Relator similarly does not sufficiently allege that Defendants fraudulently induced the VA, TRICARE, and Medicare and Medicaid to enter into contracts in connection with the sale and supply of Gamunex. *See* AC ¶ 164. As previously stated, where a relator's "fraudulent inducement

claim and his other [FCA] claims rest on the same alleged violations," the relator's "fraudulent inducement claim . . . rises and falls with his other [FCA] claims." *Foreman*, 2021 WL 5406437, at *20 n.9. Here, Relator's allegations related to the government contracts rest on the same allegations of cGMP violations as do his FCA claims brought under the implied certification theory. *See* AC ¶ 165 ("Had the United States been aware of the Defendants' fraudulent statements and submissions, it would not . . . have entered into the contracts . . . with the VA, TRICARE, and CMS"). For that reason, they are insufficient to state a claim under the FCA.

Moreover, Relator's specific allegations regarding the contracts into which Defendants' entered lack detail regarding the negotiations of the contracts at issue and the terms of those contracts. Relator's complaint contains mention of only one specific contract into which Defendants entered with the VA, and that allegation fails to expressly identify the material misrepresentation that induced the VA to enter that contract. AC ¶ 85 ("[T]he VA awarded Grifols a contract that requires it to comply with all applicable federal, state and local laws, executive orders, rules and regulations applicable to Grifols' duties under that VA contract."). The sparse allegations regarding the contracts at issue lack sufficient particularity to show how any misrepresentations would be material to the government's decision to enter into the relevant contracts, as required to meet Rule 9(b)'s standard. *See United States ex rel. Tessler v. City of New York*, 712 F. App'x 27, 29 (2d Cir. 2017) (summary order) ("To comply with Rule 9(b), the complaint must be supported by more than 'conclusory statements' or 'hypotheses,' and it must set forth 'particularized allegations of fact.'" (quoting *Ladas*, 824 F.3d at 26–27)).

Accordingly, Relator has not pleaded that Defendant's made material misstatements as required to state an FCA claim based on the fraudulent inducement theory.

B. Relator Does Not Adequately Plead a Violation of the Reverse False Claims Provision of the FCA

Relator has not sufficiently alleged a violation of the reverse false claims provision of the FCA. Liability under that provision is established where a defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). "To state a such a claim, Relator must allege (1) 'the defendant made a false record or statement (2) at a time that the defendant had a presently-existing obligation to the government—a duty to pay money or property.'" *United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.,* No. 14CV6646BMCSJB, 2021 WL 3240280, at *4 (E.D.N.Y. July 30, 2021) (quoting *United States ex rel. Piacentile v. Amgen, Inc.*, 336 F. Supp. 3d 119, 135 (E.D.N.Y. 2018)). "A 'duty to pay' . . . 'must be formally "established" before liability can arise.'" *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.,* 318 F. Supp. 3d 680, 703 (S.D.N.Y. 2018) (quoting *U.S. ex rel. Barrick v. Parker–Migliorini Int'l, LLC*, 878 F.3d 1224, 1231 (10th Cir. 2017)). Where a Relator "has not stated a claim for violation of the FCA[,] it cannot have alleged an obligation to pay money to the government." *United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, No. 14CV6646BMCSJB, 2021 WL 3240280, at *4 (E.D.N.Y. July 30, 2021).

Here, because Relator does not state a claim for a violation of the Sections 3729(a)(1)(A) and (B) of the FCA, Relator cannot sufficiently allege that Defendants had an obligation to pay money to the government. Relator alleges that Defendants "knowingly submitted false and fraudulent claims that allowed each of them to receive greater reimbursement than they were entitled to," and that those excess amounts are "overpayments that should have been returned" under the Social Security Act. AC ¶ 153. In other words, Relator's theory is that Defendants are obligated to repay the funds because Defendants received them through fraud in the first place. But, as previously explained,

Relator does not adequately plead that those initial payments were obtained through fraud, so he necessarily has not pleaded that Defendants were obligated to repay them. *See United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 249–50 (2d Cir. 2019) ("[Relator]'s reverse false claim theory thus fails for the same reason that his other FCA claims fail . . . . [T]he SAC does not plausibly allege that Defendants-Appellees caused the submission of false claims to the federal government. Accordingly, the SAC does not plausibly allege that Defendants-Appellees had any obligation to repay to the federal government any funds it received, directly or indirectly, as a result of the Medicaid claims it submitted[.]"), *cert. denied*, 140 S. Ct. 1296 (2020)). Accordingly, Plaintiff has not sufficiently pleaded a claim under the reverse false claims provision of the FCA.[7]

[7] Because the Court has dismissed all of the Counts in Relator's Complaint, it need not determine whether Relator has alleged grounds to pierce the corporate veil. *See* Mot. 22–23. Nevertheless, the Court is skeptical that Relator can properly attribute the allegedly fraudulent conduct in this case to "Grifols," which he defines to include four separate Grifols' entities—Grifols, S.A., Grifols Shared Services North America, Inc., Grifols Biologicals, LLC, and Grifols USA LLC. AC 1, ¶¶ 3–6 . To satisfy even the most liberal pleading standards, a complaint "allege the nature of *each particular* defendant's misconduct." *Holmes v. Allstate Corp.*, No. 11 CIV. 1543 LTS DF, 2012 WL 627238, at *22 (S.D.N.Y. Jan. 27, 2012) report and recommendation adopted, No. 11 CIV. 1543 LTS DCF, 2012 WL 626262 (S.D.N.Y. Feb. 27, 2012) (emphasis added) (explaining requirements for pleading under Rule 8(a)). Relator does not identify which defendant is responsible for the specific misconduct alleged.

Instead, Relator alleges that the four entities are "alter egos" such that the corporate veil can be pierced. In support of that argument, Relator relies on *United States v. TEVA Pharm. USA, Inc.*, 2016 WL 750720 (S.D.N.Y. Feb. 22, 2016) ("*TEVA*") for two dubious propositions: first, that Rule 8(a), not Rule 9(b), applies to allegations regarding each defendant's conduct in a case alleging fraud; and second, that general allegations regarding the corporate affiliations between two entities is sufficient to allege veil piercing. Opp'n 22. As to the first, the Court questions *TEVA*'s unsupported conclusion that Rule 8(a), and not Rule 9(b) applies because "the alleged fraud is the filing of false claims, not the affiliation among the named defendants." *TEVA* at *12. A more logical conclusion would seem to be that a complaint alleging fraud must identify, with particularity, the specific defendant that undertook specific fraudulent conduct. *See SEC v. U.S. Envtl., Inc.*, 82 F. Supp. 2d 237, 241 (S.D.N.Y. 2000) (concluding that a plaintiff alleging fraud "must satisfy Rule 9(b) as to each individual defendant, and cannot do so by making vague allegations about the defendants as a unit . . . .").

Second, the *TEVA* court did not consider whether the relator could pierce the corporate veil; rather, the only question in that case was whether the defendants had failed to allege the acts by defendants in sufficient detail to satisfy the relevant pleading standard. *TEVA* at *11–12. In the Second Circuit, a relator seeking to pierce the corporate veil must allege "(1) the owners exercised complete domination of the corporation in respect to the transaction attacked; and (2) that such domination was used to commit a fraud or wrong against the plaintiff which resulted in plaintiff's injury." *United States ex rel. Raffington v. Bon Secours Health Sys., Inc.*, 285 F. Supp. 3d 759, 769 (S.D.N.Y. 2018) (quoting *In re Morris v. N.Y. State Dep't of Taxation & Fin.*, 82 N.Y.2d 135, 141 (1993)). Relator's general allegations regarding Grifol's organizational structure, *see* AC ¶¶ 3–16, do not readily lead to the conclusion that the parent company used any purported "domination" to ensure that allegedly false claims were submitted to the Government.

IV. LEAVE TO AMEND

The Court grants Plaintiff leave to replead the dismissed claims. *See Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991) ("It is the usual practice upon granting a motion to dismiss to allow leave to replead."); see also Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave [to amend] when justice so requires."). While leave may be denied "for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party," those circumstances do not apply in this case. *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014) (citation omitted). Any amended complaint must be filed no later than fourteen days from the date of this order.

V. CONCLUSION

As stated above, Relator has not sufficiently alleged that Defendants claims for payment to government programs that contained records or statements material to a fraudulent claim. That deficiency is fatal to all of Relator's claims. Accordingly, Defendants' motion to dismiss Relator's complaint is GRANTED.

The Clerk of Court is directed to terminate the motion pending at Dkt. No. 72.

SO ORDERED.

Dated: December 8, 2021
New York, New York

GREGORY H. WOODS
United States District Judge